



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,805	03/26/2007	Menachem Rubinstein	057878-000033-US	8352
50828 7590 01/21/2010				
DAVID S. RESNICK NIXON PEABODY LLP 100 SUMMER STREET BOSTON, MA 02110-2131				
EXAMINER				
JIANG, DONG				
ART UNIT		PAPER NUMBER		
1646				
MAIL DATE		DELIVERY MODE		
01/21/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,805

Applicant(s)

RUBINSTEIN ET AL.

Examiner

DONG JIANG

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

The request filed on 10 November 2009 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/584,805 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 10 November 2009 is acknowledged and entered. Following the amendment, claim 31 is amended.

Currently, claim 31 is pending and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Sims et al., US 2002/0098185 A1 (7/25/02, provided by applicants), and further in view of Dombroski, for the reasons of record set forth in the last Office Action mailed on 5/20/09/, at pages 3-5.

Applicants argument filed on 10 November 2009 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 3-5 of the response, the applicant presents similar argument as that in the previous response that Sims includes description of the genus "IL- 18 antagonists", a genus of combinations of IL-18 antagonist with a large additional genus of compounds, that the subgenus claimed in this application is the specific combination of IL-18BP (a subgenus of IL-18 antagonists) and anakinra (which can be considered as a subgenus of the "compounds IL- 18 antagonist can be combined with"), that Sims only describes a general combination of IL-18 antagonists, not indicating any specific combinations with IL-18BP. Applicants further argue that Dombroski does not assist one skilled in the art to define the selection of either a specific IL-18 antagonist or any of the compounds it could be combined with. This argument is not persuasive because Sims clearly teaches a general combination of IL-18 antagonists with IL-1 antagonists, and the antagonists in each genus share the same functional property, i.e., antagonizing IL-18 and IL-1, respectively. Both IL-18 antagonists and IL-1 antagonists are known for their use in disease treatment such as RA. Thus, it would be instantly obvious that any species in each genus can be combined for disease treatment such as RA in the absence to the contrary. It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

At pages 5-6 of the response, the applicant that the Examiner also alleged that a person of ordinary skill in the art would have been motivated to combine IL-18BP with anakinra "for disease treatment such as rheumatoid arthritis as Sims and Dombroski teaches [sic] that both antagonists of IL-1 such as anakinra (Kineret) and an antagonist of IL- 18 such as IL- 18BP can be used for treating disorders such as rheumatoid arthritis, that this reasoning is against the teachings in the prior art (discussed in the previous response), which specifically teaches that

anakinra should not be combined with many of the compounds used to treat arthritis and listed in Dombroski as well as Sims, specifically, Exhibit I (submitted with the previous response) states that "Kineret should not be used with medicines called Tumor Necrosis Factor (TNF blocking agents) such as ENBREL® (etanercept), Humira TM (adalimumab), or Remicade® (infliximab). This argument is not persuasive because it is irrelevant as TNF inhibitors are not IL-18 antagonists. Whether anakinra and IL-18BP can be combined does not flow logically from those which are completely different chemical entities.

Applicants further argue, on page 6 of the response, that the specification particularly discusses the mechanisms of monotherapy using IL-1 inhibitors and IL-18 inhibitors alone, and states that the combination therapy with IL-1 antagonist and IL-18BP overcomes the disadvantage of using IL-1Ra in treatment of RA. This argument is not persuasive because it is irrelevant. As addressed in the last Office Action, the combined teachings of the prior art teach the claimed composition, and "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Examiner Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
1/18/10